DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-20 and 23, as they are drawn to a method of classifying an individual comprising analyzing the nucleic acid of the sample for nucleotide polymorphisms in the gene FKBP51 or in a haplotype block comprising the gene encoding FKBP51.

Group 2, claim(s) 1-7, 21, 22, and 23, as they are drawn to a method of classifying an individual comprising determining the expression level of FKBP51 in said sample.

Group 3, claim(s) 1-23, as they are drawn to a method of classifying an individual comprising analyzing the nucleic acid of the sample for nucleotide polymorphisms in the gene FKBP51 or in a haplotype block comprising the gene encoding FKBP51 AND comprising determining the expression level of FKBP51 in said sample.

Group 4, claim(s) 24, in part, drawn to a nucleic acid molecule comprising SEQ ID NO: 116.

Group 5, claim(s) 24, in part, drawn to a nucleic acid molecule comprising SEQ ID NO: 118.

Group 6, claim(s) 24, in part, drawn to a nucleic acid molecule comprising SEQ ID NO: 116 and SEQ ID NO: 118.

Group 7, claim(s) 25 and 26, in part, drawn to a nucleic acid encoding a polypeptide with the sequence of SwissProt accession Q13451, or a nucleic acid which hybridizes to the complementary strand, and use in the manufacture of a pharmaceutical composition.

Group 8, claim(s) 25 and 16, in part, drawn to a composition comprising a polypeptide encoded by a nucleic acid encoding a polypeptide with the sequence of SwissProt accession Q13451, or a nucleic acid which hybridizes to the complementary strand use in the manufacture of a pharmaceutical composition.

Group 9, claim(s) 26, in part, drawn to use of an activator of the expression of the polypeptide for the manufacture of a pharmaceutical composition.

Group 10, claim(s) 26, in part, drawn to use of an activator of the expression of the polypeptide for the manufacture of a pharmaceutical composition.

Group 9, claim(s) 26, in part, drawn to use of an activator of the polypeptide for the manufacture of a pharmaceutical composition.

Group 10, claim(s) 27, in part, drawn to a method of treating depression by administration of a nucleic acid encoding a polypeptide or a nucleic acid hybridizing thereto.

Group 11, claim(s) 27, in part, drawn to a method of treating depression by administration of a polypeptide encoded by (a) or (b).

Group 12, claim(s) 27, in part, drawn to a method of treating depression by administration of an activator of the expression of a polypeptide.

Group 13, claim(s) 27, in part, drawn to a method of treating depression by administration of an activator of the polypeptide.

Group 14, claim(s) 28, in part, drawn to use of geldanamycin or a geldanamycin derivative for the manufacture of a pharmaceutical composition for the treatment of depression.

Group 15, claim(s) 28, in part, drawn to use of an antibody for specifically recognizing FKBP52 for the manufacture of a pharmaceutical composition for the treatment of depression.

Group 16, claim(s) 28, in part, drawn to use of an aptamer for specifically recognizing FKBP52 for the manufacture of a pharmaceutical composition for the treatment of depression.

Group 17, claim(s) 29, in part, drawn a method of treating depression comprising administration

of geldanamycin or a geldanamycin derivative.

Group 18, claim(s) 29, in part, drawn a method of treating depression comprising administration of an antibody for specifically recognizing FKBP52.

Group 19, claim(s) 30, in part, drawn a method of treating depression comprising administration of an aptamer for specifically recognizing FKBP52.

2. The inventions listed as Groups 1-19 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: WO03/082210 (as cited in IDS) teaches four polymorphisms in FKB51 and methods of classifying individuals as having schizophrenia or not, including rs3777747 mentioned in the instant claims (see pages 104-105, Table 2 and

throughout). Thus, at least claim 1 is anticipated by the prior art and so there is no special technical feature that joins all of the claims.

Further restriction requirement for groups 1 and 3:

The group includes claims which recite that the polymorphism or haplotype block comprises at least one SNP selected from the group of thirty different uniquely identified polymorphisms. For the purposes for restriction under lack of unity, each combination is considered a different invention, and in response to this restriction requirement, **if applicant elects group 1 or group 3, a single combination of SNP from those listed should further be elected.** The combination can contain one SNP up to all thirty, but the elected combination should be clearly stated on the record. For the elected SNP, identify their position within the gene, namely if they are in a coding or non-coding region.

Claims which are generic to methods using any combination will be treated as linking claims, and if a linking claim becomes allowable, the restriction among methods using the combinations will be withdrawn. Likewise, if the elected combination becomes allowable, any combination that includes the elected combination will be rejoined consonant with combination/subcombination practice as set forth in the MPEP.

3. The inventions within group 1 and 3 which used different combinations of polymorphisms do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The feature that joins all of these is that they are methods for classifying an individual based on looking at different nucleotides present at positions known to be polymorphic within the FKBP51 gene. However, this is not a special technical feature because WO03/082210 (as cited in IDS) teaches four polymorphisms in FKB51 and methods of classifying individuals as having schizophrenia or not, including rs3777747 mentioned in the instant claims (see pages 104-105, Table 2 and throughout).

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species for classifying:

(a) predicting the response to therapy

(b) selecting for a clinical trial

(c) predicting the predisposition for an elevated number of episodes of depression

Species for primers pairs and Species for extension primers and Species for probes

Each of the individual primer pairs and extension primers listed in claims 16 and 18 are unique species for the primer pairs and extension primers, respectively. Likewise, each of the probe sets listed in claim 20 are unique species for probe sets. Applicant is required to elect a single primer pair, a single extension primer and a single probe set, all of which are directed towards the detection of the **same polymorphism.**

Species for expression level to be determined

(a) mRNA expression level

(b) protein expression level

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

Species for classifying:
(a) claim 2
(b) claims 3, 5, 6, 7
(c) claim 4
The following claim(s) are generic to any classifying: 1, 8-23

Species for primers:
Claims 1-23 are generic to all species of primers, extension primers and probes, with claims 16, 18, and 20 specifically enumerating the species in the alternative.

Species for expression level:
(a) claim 21
(b) claim 22
Generic: 1-20 and 23

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: WO03/082210 (as cited in IDS) teaches four polymorphisms in FKB51 and methods of classifying individuals as having schizophrenia or not, including rs3777747 mentioned in the instant claims (see pages 104-105, Table 2 and throughout). Thus, since the method of classifying of claim 1 is anticipated, there is no special technical feature that joins all of the claimed methods of classification, to which these species relate.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. There are multiply independent claims and non-statutory use claims in the instantly

restricted claim set. The examiner has made a good faith effort to properly group these improper claims. Applicant is advised to correct these claims prior to the commencement of prosecution on the merits. When they are amended, further restriction may be warranted.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday, Tuesday, or Wednesday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached by calling (571) 272-0735.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Juliet C. Switzer/
Primary Examiner
Art Unit 1634

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